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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,822	12/31/2003	John Pafford	1842-0029	9366
28078	7590	10/29/2008	EXAMINER	
MAGINOT, MOORE & BECK, LLP CHASE TOWER 111 MONUMENT CIRCLE SUITE 3250 INDIANAPOLIS, IN 46204				HOFFMAN, MARY C
3733		ART UNIT		PAPER NUMBER
10/29/2008		MAIL DATE		DELIVERY MODE
				PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/749,822	PAFFORD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MARY HOFFMAN	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 July 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3-8,31 and 32 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3-8,31 and 32 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 31 December 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-8 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlapfer et al. (U.S. Patent No. 5,501,684).

Schlapfer et al. disclose a dynamic stabilization system for stabilization comprising a stabilization element (FIG. 8, ref. 37) capable of spanning between at least two vertebrae and defining a longitudinal axis along the length of the element: at least two bone anchors (ref. 1e), each having a bone engagement portion (lower half); and at least two connectors (see FIG. 8, attachment mechanisms fixing ref. 1e to the stabilization element, ref. 37) for connecting a corresponding one of the bone anchors to the stabilization element, at least one connector including; a bearing member (ref. 51) attached to the stabilization element; a compressible flexible element (ref. 2e) supported within the bearing member with the bone anchor extending through the flexible element, the flexible element contacting the bearing member substantially along the longitudinal axis of the stabilization element to permit relative pivoting between the corresponding bone anchor and the stabilization element and the flexible element is configured to expand along the longitudinal axis as the element is compressed; and an adjustment

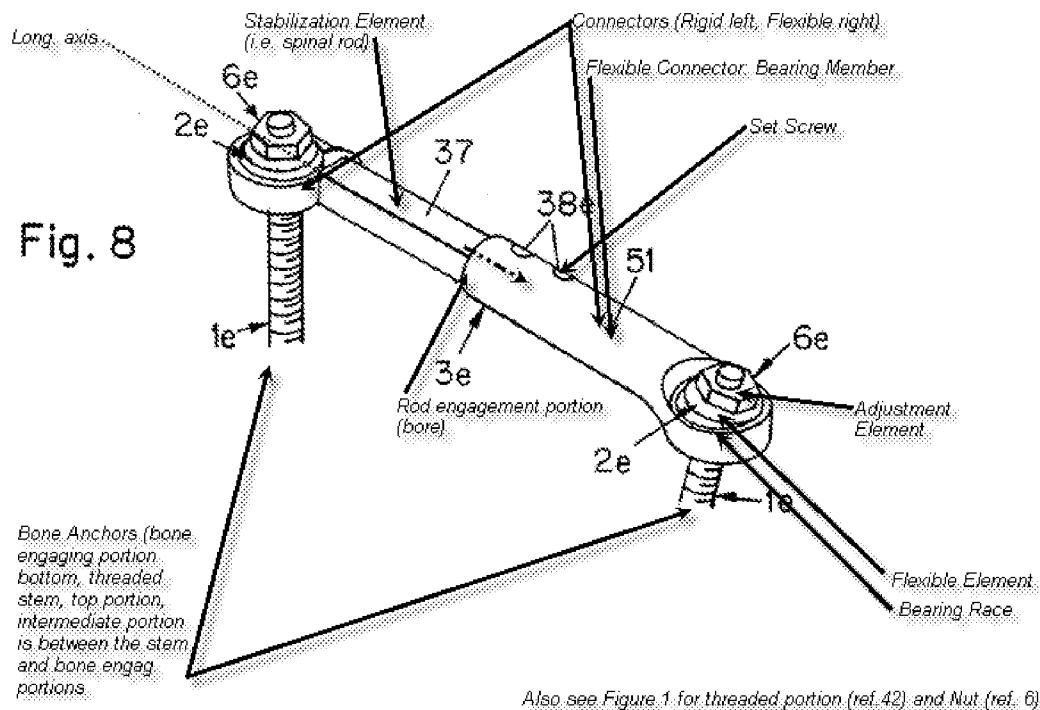
element (ref. 6e) configured to compress the flexible element to thereby adjust the flexibility of the flexible element to adjust the amount of the relative pivoting (claim 1).

The stabilization element includes an elongated spinal rod, the bearing member is a rod end bearing including a rod engagement portion; and the flexible element is a bearing element of the rod end bearing (claim 3). The bearing element is received within a bearing race (integral with ref. 51, the surface along circumference of the bore in which ref. 2e is placed) of the rod end bearing; and the adjustment element is arranged to compress the bearing element within the bearing race (claim 4). The rod engagement portion includes a bore for receiving a portion of the spinal rod therein and a set screw (ref. 38e) for clamping the spinal rod within the bore (claim 5). The at least one of the bone anchors includes a stem having a threaded portion (see FIG. 1, ref. #42); the flexible element includes a bore for receiving the stem therethrough; and the adjustment element includes a nut engaging the threaded portion and arranged to compress the flexible element as the nut is threaded onto the threaded portion (claim 6). The at least one of the bone anchors includes an intermediate portion (see FIG. 1, ref. 11) between the stem and the bone engagement portion, the intermediate portion configured to support the flexible element so that the flexible element is compressed between the intermediate portion and the nut when the nut is threaded onto the threaded portion (claim 7). Another of the connectors is configured to substantially rigidly connect one of the bone anchors to the stabilization element (see FIG. 8, left side) (claim 8). The flexible element has a substantially spherical outer surface; and the bearing race defines a substantially spherical inner surface engaging the outer surface of the flexible

Art Unit: 3733

element (claim 31). The flexible element is compressible along an axis substantially perpendicular to the longitudinal axis; and the adjustment element is configured to operate along the substantially perpendicular axis (claim 32).

Schlapfer et al. (Patent 5,501,684)



### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schlapfer et al. (U.S. Patent No. 5,501,684).

Schlapfer et al. discloses the claimed invention except for the bearing race being mounted within the bearing member (i.e. a bearing race that is not integral with the bearing member). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bearing race not being integral with the bearing member, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

### ***Response to Arguments***

Applicant's arguments filed 07/22/2008 have been fully considered but they are not persuasive. Applicant's amendments to the claims filed 07/22/2008 (see underlining in above rejection) do not appear to overcome the Schlapfer et al. reference. Applicant argues that the Schlapfer et al. reference does not show a flexible element that is compressible and configured to expand along the longitudinal axis as the element is compressed. Rather, Applicant argues that element ref. #2 expands via slits ref. # 24. Applicant also argues that the adjustment element is not configured to compress the flexible element to thereby adjust the flexibility of the element to adjust the amount of relative pivoting. The examiner respectfully disagrees. The element denoted by ref. #2 is clearly compressed against the inner walls of the borehole ref. #31 that receives the element, for example, as seen in FIG. 4. For something to be considered "compressible"

*it must merely be capable of being compressed, squeezed, or pressed against something or into a smaller space.* To be compressible, the element does not need to be made of a specific material, as suggested by Applicant; moreover, Applicant is not claiming any specific material, like silicon or any other elastomeric material, in the claims. Therefore, the element is “compressible” because it presses against the inner walls of borehole ref. #31 to lock the components together. Also, element ref. #2 expands in all directions as a result of its slits to press against the inner walls of borehole ref. #31, including the direction along the longitudinal axis, and can therefore be considered flexible. Thus, the element is configured to expand along the longitudinal axis as the element is compressed via the adjustment member. In addition, the adjustment member denoted by ref. #6 appears configured to compress the flexible element to thereby adjust the flexibility of the flexible element because the adjustment member forces the element to expand and therefore compress against the inner walls of borehole ref. #31. Because the element becomes increasingly tightened until it is locked in the borehole due to its slit expansion and resulting compression against the inner walls of the borehole, the adjustment nut can be considered to adjust the flexibility of the flexible element to adjust the amount of relative pivoting as it produces this tightening/locking action.

Regarding claim 4, the claims do not specify that the bearing race is non-integral with the bearing member. Therefore, it is irrelevant whether the reference includes those features or not.

Regarding claims 6-7, the nut #6 of Schapfler is clearly “arrange” to compress the flexible element as it is tightened.

Regarding claim 32, the flexible element is clearly compressible along an axis substantially perpendicular to the longitudinal axis; and the adjustment element is configured to operate along the substantially perpendicular axis as it is threaded to tightened and lock the compressible element.

The rejections are deemed proper.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MCH/  
/Eduardo C. Robert/  
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